

Docket No.: ECV-5631

BEFORE THE UNITED STATES PATENT AND TRADEMARK OFFICE

5 In re Application of: Diana Nguyen-Thien-Nhon, et al.

) Group Art Unit: 3738

Application No.: 09/745,386

) Examiner: A. Stewart

Filing Date: December 21, 2000

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For: HEART VALVE HOLDER THAT RESISTS SUTURE
LOOPINGREPLY BRIEF

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MS Appeal Brief -Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

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Dear Sir:

This is a reply to the Examiner's Answer dated May 16, 2003 in the Appeal in the above-referenced application. Only those sections that require a reply to the Examiner's Answer are included.

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II.

RELATED APPEALS AND INTERFERENCES

Applicant's opening Appeal Brief included a statement concerning related appeals or interferences; namely that there are none.

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VII.

GROUPING OF CLAIMS

As stated in Applicants' opening Appeal Brief, Claims 2-4 and 24-25 depend from and stand or fall together with independent claim 1.

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VIII.

ARGUMENT

The Examiner maintains his rejections of Claims 1-4, 24, and 25 under 35 U.S.C. section 103(a) as being obvious in view of U.S. Patent No. 4,865,600 to Carpentier, et al. ("Carpentier et al.").

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Reply Brief
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GROUP 3700

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The Examiner has described and characterized Carpentier, et al. in a certain manner which requires comment. Carpentier, et al. discloses a prosthetic heart valve 13, a valve holder 15, and elongated flexible means 17 (i.e., three sutures) for attaching the heart valve to the holder. The heart valve 13 has an inflow end, an outflow end, a flow axis, an annular suture ring 25, and a plurality of axially-extending commissure posts 27 terminating in free end portions 29. The holder sutures 17 have opposite ends 77 (Fig. 8) which are tied to the holder. A length of each suture extends generally axially through one of the commissure posts 27 to the free end portion 29 thereof. As shown in Figs. 2 and 8, the suture then extends between adjacent commissure supports 27, and the portion of the suture between each pair of commissure supports 10 forms a portion of a suture loop guard 19. When the valve 13 is in position, the surgeon sews the suture ring 25 to the annulus 107 using sutures 109. After delivery of the valve to the annulus and during the attachment procedure, the suture loop guard 19 materially reduces the likelihood of looping of one of the attachment sutures 109 (see Figs. 10-11 and column 6, lines 5-11) around the commissure supports 27 so as to impair operation of the heart valve 13. There is no 15 mention of protecting against suture looping during the delivery procedure, when the valve is being passed down an array of pre-embedded attachment sutures (commonly known as the parachute array).

The Carpentier, et al. reference does not teach or suggest the claimed configuration in which "... each length of material [has] a first segment extending directly between adjacent 20 commissure posts and crossing over (i.e., intersecting) each adjacent length of material ..." (Claim 1, lines 8-10, emphasis added). Rather, as seen at the bottom of Fig. 8 in Carpentier, et al., the lengths of suture in the Carpentier design diverge in opposite directions at the commissure tips without crossing over. Applicants' cross-over configuration provides an advantageous improvement over the Carpentier, et al. design, in that it reduces the chance of 25 suture looping during the valve delivery procedure.

The Examiner argues on page 4 of the Answer that Applicants have "failed to show the improvement...with respect to the Carpentier, et al. reference, *except by intersecting the two sutures together.*" (emphasis added) This statement is dismissive and conclusory at the same

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time. Applicants assert that the improvement is in fact because of the suture cross-over. For the Examiner to admit the presence of such a difference, but to then waive it away as a non-improvement has no proper foundation.

5 The Examiner incorrectly states on page 4 of the Answer that the application did not disclose that Carpentier, et al. had suture looping problems solved by the present invention. But in the paragraph on page 2 describing Carpentier, et al., the following passage appears: "However, even when the commissure posts are constricted, slack in the array of sutures, for example, may lead to looping of sutures around one of the cloth-covered commissure posts, which interferes with the implantation procedure." Thus, the problem of suture looping in
10 Carpentier, et al. was disclosed.

The Examiner also states that Carpentier, et al. in column 1, lines 64-68 discloses a design capable of resisting suture looping. Applicants don't dispute that Carpentier et al. discloses at least one way to reduce suture looping. However, Carpentier, et al. reduces the likelihood of suture looping because the holder sutures pull the commissure posts inward, not
15 because of the particular pathway and interaction of sutures between commissure posts. Moreover, as stated above, Carpentier, et al. focuses on suture looping AFTER delivery and during the attachment (sewing) procedure. In column 6, lines 5-11, "[w]ith the valve 13 properly positioned, the surgeon sews the suture ring 25 to the annulus 107 using sutures 109 and known suturing techniques. During this suturing operation, the suture loop guard 19 materially reduces
20 the likelihood of looping of one of the sutures 109 around the commissure supports 27 so as to impair operation of the heart valve 13." That is, the commissure post constriction helps prevent suture looping during the attachment procedure because the commissure posts are pulled inward away from the area behind the sewing ring where the sutures 109 loop through the annulus 107 (see Fig. 10).

25 In contrast, the present invention crosses the sutures over at the commissure tips to reduce the likelihood of suture looping *during delivery*. Crossing over the sutures provides a barrier of sorts at each commissure tip that better resists looping around one of the array of slack sutures.

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The purpose of the Examiner's discussion of whether or not the Carpentier, et al. design suffers problems with slack in the array of sutures is not clear. Carpentier, et al. may have problems with slack sutures, as will most any mitral valve delivered outflow end first along an array of sutures. The present invention reduces the likelihood of suture looping from such slack.

5 If there is a flaw in the Carpentier, et al. design it is because it does not include the crossed-over holder sutures as described and claimed in the present application.

The Appeal Board is again urged to consider the Declaration of Diana Nguyen under 37 C.F.R. §1.132 in support of the arguments raised in the Amendment After Final. The Declaration was filed in response to the Examiner's contention in the Final Office Action that
10 one of skill in the art would expect the invention to perform equally well with the sutures not crossing each other. Diana Nguyen is one of skill in the art and her Declaration under penalty of perjury refutes the Examiner's unsupported assertion that the suture cross-over provides no performance enhancement over the non-cross-over design. For example, Ms. Nguyen states that the suture cross-over defines a planar barrier to suture looping closely adjacent each commissure
15 tip. Such language is in the application and has been previously noted and should be given weight in this appeal.

Applicants thus request that the Examiner's rejections of pending claims 1-4, 24 and 25 be overturned.

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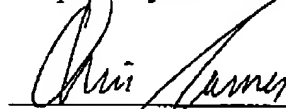
Date:

July 15, 2003

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Respectfully submitted,



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